QbD / CMC Panel Questions and Answers

When Will QbD Become a Requirement and How Will it be Enforced?

- FDA/GPhA has developed a QbD example for an IR product
- The draft QbD example for an MR product is to be completed by the end of 2010. Discussion with GPhA is expected in 2011
- The QbR questions will be revised in 2011 to incorporate QbD elements. Discussion with GPhA is expected in 2011 and 2012
- We expect that the revised QbR review system will be fully implemented by January 2013

Should Generic Applicants Expect to See a Concrete QbD Guidance?

- OGD will publish the revised QbR questions
- OGD will revise the frequently asked question paper to explain information that should be submitted to answer each question

How Does the FDA Propose Addressing the Incompatibility of “First to File" and QbD?

- The FDA will publish a federal register notice to clarify ANDA submission requirements

Is OGD Open to Collaborative Discussion and Industry Input?

- Extensive discussion and input took place during the QbR development. OGD and GPhA collaborated in developing a QbD example for an IR product.
- The same approach will be used for developing the QbD example for an MR product and revising QbR questions
- It is important for ANDA applicants to review and provide comment to the QbD examples and QbR questions

Will There be Room for Discussion About QbD?

- GPhA and OGD have organized three roundtable discussions in 2009 – 2010
- GPhA and OGD organized an QbD workshop in May 2010
- GPhA and OGD will organize roundtable discussions on the QbD example for a MR product
- GPhA and OGD will organize QbR and QbD workshops
- Please be actively involved in any future roundtable discussions and workshops

What QbD Elements Are Required and What Are Optional?

- Required
  - Quality target product profile (QTPP)
  - Product design and understanding
  - Process design and understanding
  - Control strategy, including justification
- Optional
  - Design Space
  - Process Analytical Technology

How is the FDA Going to Handle the Different Interpretations of QbD by the Different Companies?

- OGD will use the same approach for all ANDAs regardless of applicants (companies)

Can FDA Clearly Define QTPP?

- QTPP – ICHQ8(R2) – "…forms the basis of design for the development of the product." Considerations include:
  - Intended use, route of admin, dosage form, delivery system, strengths, container closure, release or delivery of active and attributes affecting PK, and quality criteria.
  - Simply stated – QTPP is predetermined set of targets based on the intended use of the product under development with respect to knowledge and characterization of the RLD

Can FDA Clearly Define Critical Parameters?

- ICHQ8(R2)
  - A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality.

Can FDA Clearly Define Prior Knowledge?

- OGD considers it as reliable information based on prior example of scientific studies. It could be internal to an applicant
- It should be reiterated again that generic industry needs to step up and provide practical examples

What Are OGD's Expectations for Scored Tablets?

- Generic configuration is to be the same as the RLD
- Quality and Performance Expectations
  - Suitability of splitting
  - Uniformity
  - Mass loss
  - Suitable for intended use
- Development Studies
- Guidance under development